

**REMARKS**

Applicant respectfully requests the Examiner to reconsider the merits of the objections and rejections in view of the foregoing amendments and following remarks.

Upon entry of the foregoing amendment, claims 57, 58, 63-69, 71, 74, 76, 77 & 79-84 are pending in the application. New claims 83 and 84 are added. Claims 59-61, 70, 72, 73, 75 & 78 are cancelled without prejudice to or disclaimer of the subject matter therein. Claims 64, 71, 76 & 77 are amended.

Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter.

Support for the amendments to the claims and new claims can be found throughout the specification and in the claims as originally filed. In particular, support for the amendment to claims 64 and 71 can be found, *inter alia*, in the specification on page 31, line 16 to page 32, line 10. Applicants amended claim 76 to correct a dependency in light of an instant claim cancellation. Applicants amended claim 77 to comply with a certain informality and to enhance the precision of the described invention. Support for new claims 83 and 84 can be found, *inter alia*, in the specification on page 23, lines 4-22.

Based on the instant amendment and remarks, Applicants respectfully request that the Examiner withdraw the outstanding objections and rejections.

**I. Objections**

**A. Objection to the Abstract**

Applicants set forth an amendment to the abstract in their Amendment and Reply filed August 24, 2004 (the "Reply of August 24, 2004"). However, the Office Action maintains the objection to the abstract of the invention on the basis that it should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. Applicants thank the Examiner for suggesting to add the phrase "truncation fragments" to the abstract. Accordingly, Applicants have amended the abstract in the instant Reply to delete the term "variants" and add the phrase "truncated fragments." Therefore,

Applicants respectfully request the Examiner to withdraw the objection to the abstract of the invention.

**B. Objection to the Title**

Applicants amended the title of the invention in the Reply of August 24, 2005. However, the Office Action maintained the objection to the title of the invention on the ground that it is not descriptive of the instant invention. Applicants have amended the title in the instant Reply to include a reference to Cry2Ae insecticidal proteins, thereby enhancing the precision of the description of the invention in the title. Consequently, Applicants respectfully request the Examiner to withdraw the objection to the title of the invention.

**C. Objection to the Claims**

The Office Action sets forth objections to claims 71, 73, 75 & 77 based on certain informalities.

The Office Action maintains the objection to claim 71 on the basis that, according to the Office Action, the article before "leader" in part (b) is improper. Claim 71 recites "a" before the term "leader" in part (b). The Office Action states that "[u]nless there is more than one leader sequence from the Petunia chlorophyll a/b binding protein gene, 'the' is correct, just as 'the' is correct before 'chlorophyll' in that phrase." Office Action, page 4. Applicants respectfully disagree.

First, use of the term "the" before "leader sequence" does not accurately reflect the claimed invention because the claimed invention encompasses more than only one exact leader sequence from the gene recited in part (b) of claim 71. For example, the claimed invention includes leader sequences in addition to only the naturally-occurring leader sequence. Thus, as disclosed in the specification, Applicants are claiming "*a* leader sequence," which one of skill in the art would clearly recognize includes deletions or some replacements without affecting the proper functionality of the chimeric gene. On the other hand, Applicants use the phrase "*the* chlorophyll a/b binding protein gene" in part (b) of claim 71 to refer to the particular Petunia gene identified in the art.

Second, as stated in the Reply of August 24, 2004, a description of "a leader sequence" is clearly set forth in the specification, which states, for example, "several chimeric gene constructs were inserted in *Agrobacterium* strain plasmids. These constructs included: constructs pACS9 and pACS11 wherein the cry2Ae coding sequence . . . was functionally linked to . . . a leader sequence from the chlorophyl a/b binding protein gene from Petunia (Harpster et al., 1988)." Specification, page 31, line 17 to page 32, line 4 (emphasis added).

Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the objection to claim 71.

The Office Action also maintains the objection to claim 73 on the ground that, according to the Office Action, claim 73 has an improper article before "3" in line 2. The Office Action states that "[u]nless there is more than one 3' transcript termination and polyadenylation region of the CaMV 35S gene 'the' is correct, just as 'the' is correct before '35S' in that phrase." Office Action, page 4. Applicants have cancelled claim 73 in the instant Reply. Further, Applicants respectfully assert that the phrase "a 3' transcript termination and polyadenylation region of the 35S gene from Cauliflower Mosaic Virus," now recited in step (e) of amended claim 71, is free from any objections based on the use of the term "a" before "3' transcript termination and polyadenylation region."

First, use of the term "the" before "3' transcript termination and polyadenylation region" does not accurately reflect the claimed invention because the claimed invention includes more than only one exact 3' end region. For example, the claimed invention covers 3' ends in addition to only the naturally-occurring 3' end. Indeed, the invention of claim 71 encompasses at least several 3' end regions and variations derived from the 35S gene of the CaMV virus, which would be clearly recognized by the skilled artisan. On the other hand, Applicants use the term "the" in the phrase "the 35S gene from Cauliflower Mosaic Virus" to refer to the particular CaMV gene identified in the art.

Second, as stated in the Reply of August 24, 2004, a description of "a 3' transcript termination and polyadenylation region" is clearly disclosed in the specification, which states, for example, "several chimeric gene constructs were inserted in *Agrobacterium* strain plasmids. These constructs included: constructs of pACS9 and pACS11 wherein the cry2Ae coding sequence . . . was functionally linked to . . . a 3' transcript termination and polyadenylation

region of the 35S gene from Cauliflower Mosaic Virus (Sanfacon et al., 1991)." Specification, page 31, line 17 to page 32, line 6 (emphasis added).

Thus, Applicants respectfully submit that amended claim 71 is free from any objection.

Regarding the objection to claim 75, the Office Action states that the colons after "from" should be deleted. Applicants have cancelled claim 75, thereby rendering the objection to claim 75 moot. With regard to the objection to claim 77, the Office Action states that the colons after "control" should be deleted. In order to expedite prosecution, the Applicants have deleted the colons in claim 77, in accordance with the Examiner's suggestions.

The Office Action states that claim 70 is objected to as being of improper dependent form. Applicants have cancelled claim 70. Therefore, the objection to claim 70 has been rendered moot.

## **II. Rejection under 35 C.F.R. § 112, para. 2**

The Office Action states that claims 64, 66-68 & 71-78 under 35 U.S.C. § 112, para. 2, are rejected as being indefinite for failure to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The Office Action states that the rejection is repeated for the reasons set forth in the Office Action dated February 24, 2004.

As an initial matter, Applicants respectfully point out that the Office Action does not provide an explanation for the rejection of claims 65, 67 & 74 under § 112, para. 2. Thus, Applicants submit that claims 65, 67 & 74 are definite and respectfully requests the Examiner to withdraw the rejection of these claims under § 112, para. 2.

With regard to claim 64, the Office Action states that "it is unclear in claim 64 where the DNA encoding a targeting or transit peptide is located relative to the DNA sequence and the promoter." Office Action, page 5. The Office Action further states, "[i]f applicant intends that the transit peptide coding sequence be in operable linkage to the DNA encoding the Cr2Ae [sic] protein, the claim should so say." *Id.* Amended claim 64 now includes the language "a DNA encoding targeting or transit peptide which is operably-linked to said DNA." Accordingly, Applicants respectfully submit one of skill in the would understand the metes and bounds of claim 64, as amended. Consequently, Applicants request the Examiner to withdraw the rejection

under 35 U.S.C. § 112, para. 2, of claim 64 and claims 66 & 68, which depend directly or indirectly from claim 64.

Regarding claim 71, the Office Action states that "[i]t is unclear in claim 71 if the components in parts (a)-(c) are present in any order, or in operably linkage." Office Action, page 5. Amended claim 71 now includes the language "[a] chimeric gene comprising the following operably-linked elements." Thus, Applicants respectfully submit that a skilled artisan would understand the parameters of claim 71 in light of the amendment to claim 71.

Also regarding claim 71, the Office Action further states that "[c]laim 71, part (a) is indefinite in its recitation of 'derived.' It is unclear how the promoters differ from the native promoters. . . . the specification does not define promoters derived from CaMV 35S." Applicants have deleted the term "derived" from claim 71. Furthermore, amended claim 71 now recites "a 35S promoter of Cauliflower Mosaic Virus." Applicants respectfully submit that one of skill in the art would clearly understand the metes and bounds of amended claim 71. As the specification makes clear, one of skill in the art would readily discern from the phrase "a 35S promoter of Cauliflower Mosaic Virus" the forms of a promoter from the CaMV 35S gene, with different sizes or minor variations. For example, the specification teaches that "[c]himeric genes are made using well known procedures, using promoters such as the CaMV 35S (Hull and Howell, 1987)," specification, page 31, lines 8-10, and further discloses that "several chimeric gene constructs were inserted in *Agrobacterium* strain plasmids. These constructs included: constructs of pACS9 and pACS11 wherein the cry2Ae coding sequence . . . was functionally linked to the 35S2 promoter from Cauliflower Mosaic Virus (Odell et al., 1985)," specification, page 31, line 17 to page 32, line 3. Applicants therefore respectfully submit that amended the skilled artisan would readily discern the parameters of claim 71, and that claim 71 is definite.

Thus, Applicants respectfully request that the rejection of claim 71 under § 112, para. 2, be withdrawn.

The Office Action states that, regarding claim 72, "[i]t is unclear in claim 72 where the DNA encoding the TpssuAt transit peptide is located relative to the promoter, the leader sequence, and the DNA. It is also unclear for what 'TpssuAt' is an abbreviation." Office Action, page 6. Applicants have cancelled claim 72, thereby rendering the rejection to claim 72 moot. Moreover, amended claim 71, which now contains the recitation in step (c) "a DNA sequence

encoding the TpssuAt transit peptide," is definite under § 112, para. 2. Amended claim 71 recites "[a] chimeric gene comprising the following operably-linked elements: . . . a DNA sequence encoding the TpssuAt transit peptide." Thus, the location of the TpssuAt transit peptide is clear to one of skill in the art. In addition, the skilled artisan would clearly understand the meaning of the phrase "TpssuAt transit peptide" recited in claim 71. For instance, the specification explains the meaning of the term "TpssuAt" in a manner sufficient for one of skill in the art to clearly understand the meaning of the term. The specification states, "several chimeric gene constructs were inserted in *Agrobacterium* strain plasmids. These constructs included: . . . constructs of pACS12 and pACS13 with the same regulatory regions and the same cry2Ae coding region except that also a DNA sequence encoding the TpssuAt transit peptide allowing chloroplast targeting (Krebbers et al., 1988) was inserted at the 5' end." Specification, page 31, line 17 to page 32, line 9. Hence, the skilled artisan would readily discern the parameters of claim 71 as it involves the TpssuAt peptide because the TpssuAt transit peptide itself is known in the art.

Accordingly, Applicants respectfully submit that claim 71 and claim 76, which depends from claim 71 in the alternative, are definite under § 112, para. 2.

With regard to claim 73, the Office Action states that "it is unclear in claim 73 where the transcript termination and polyadenylation region is located relative to other components of the chimeric gene." Office Action, page 6. Claim 73 has been cancelled, thereby rendering the rejection of claim 73 moot. In addition, amended claim 71 now includes the language "[a] chimeric gene comprising the following operably-linked elements: . . . (e) a 3' transcript termination and polyadenylation region of the 35S gene from Cauliflower Mosaic Virus." Thus, Applicants respectfully submit that claim 71 is definite with respect to the location of the 3' transcript termination and polyadenylation region.

Applicants cancelled claim 75, thereby rendering the rejection of claim 75 under § 112, para. 2, moot.

The Office Action states that claim 78 is indefinite in the recitation of the term "derived." Office Action, page 7. However, Applicants respectfully point out that claim 78 does not contain the term "derived." *See* Reply of August 24, 2004. In any case, Applicants cancelled claim 78, thereby rendering the rejection of claim 78 under § 112, para. 2, moot.

Regarding claim 77, the Office Action states that "[i]t is unclear in claim 77, line 2, which protein, of the many that can be encoded by any DNA, is the one intended." Office Action, page 7. Amended claim 77 now contains the language "expressing in transformed plant cells an insecticidally-effective amount of said protein encoded by the DNA of any one of claims 57 or 58." Thus, one of skill in the art would clearly understand the metes and bounds of claim 77. In particular, one of skill would understand that claim 77 involves expressing the proteins encoded by the DNA of claim 57 or claim 58. As claim 57 and claim 58 are definite, the skilled artisan would clearly understand the parameters of claim 77 as referring to the proteins encoded by the DNA of claim 57 and claim 58. Therefore, Applicants respectfully submit that amended claim 77 is definite and request the Examiner to reconsider and withdraw the rejection of claim 77 under § 112, para. 2.

### **III. Rejection under 35 U.S.C. § 103**

The Office Action states that claims 57 & 58, 63-70, 74, 76, 77 & 79-82 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,593,293, issued to Baum et al. (the "Baum '293 patent") in view of Schnepf, et al., *Bacillus thuringiensis and its Pesticidal Crystal Proteins*, 62 Microbio. & Mol. Bio. Revs., 775-806 (September 1988) (the "Schnepf reference").

In particular, the position set forth in the Office Action is that

Baum et al. do not disclose fragments of the nucleic acid encoding a protein consisting of amino acids 2-49 to 632 of SEQ ID NO: 2 or of amino acids 1 to 625-631 of SEQ ID NO: 2.

Schnepf et al teach that another Cry2 protein is activated by processing at the N-terminal and C-terminal ends, with about 44 amino acids removed from the N-terminus and several being removed from the C-terminus (pg 783, right column, paragraph 1).

Office Action, page 8. Applicants respectfully traverse this rejection.

Applicants respectfully submit that, contrary to the position taken in the Office Action, the Schnepf reference does not teach that a "Cry2 protein is activated by processing . . . with about 44 amino acids removed from the N-terminus." *Id.* The Office Action states that the Schnepf reference discloses the removal of 44 amino acids on page 783, right column, paragraph

1, of the Schnepf reference. *Id.* However, this particular paragraph of the Schnepf reference to which the Office Action refers discusses Cry1A, Cry1Ac and Cry1Ia. Therefore, this particular paragraph does not teach that a "Cry2 protein is activated by processing . . . with about 44 amino acids removed from the N-terminus." Accordingly, the Schnepf reference does not disclose a DNA sequence encoding a truncated insecticidal Cry2Ae protein consisting of the amino acid sequence of the protein of SEQ ID NO: 2 from amino acid position 1 to an amino acid position between amino acid position 625 and amino acid position 632, nor does the Schnepf reference disclose a DNA sequence encoding a truncated insecticidal Cry2Ae protein consisting of the amino acid sequence of the protein of SEQ ID NO: 2 from an amino acid position between amino acid position 1 and amino acid position 50 to amino acid position 632. Consequently, the Baum '293 patent in view of the Schnepf reference neither teaches nor suggests all of the features of independent claims 57 and 58.

In particular, neither the Baum '293 patent nor the Schnepf reference, alone or in combination, teaches or suggests the features of claim 57 involving a DNA sequence encoding a truncated insecticidal Cry2Ae protein consisting of the amino acid sequence of the protein of SEQ ID NO: 2 from amino acid position 1 to an amino acid position between amino acid position 625 and amino acid position 632. Furthermore, neither the Baum '293 patent nor the Schnepf reference, alone or in combination, teaches or suggests the features of claim 58 involving a DNA sequence encoding a truncated insecticidal Cry2Ae protein consisting of the amino acid sequence of the protein of SEQ ID NO: 2 from an amino acid position between amino acid position 1 and amino acid position 50 to amino acid position 632.

Applicants point out that claim 70 has been cancelled. Thus, the rejection of claim 70 under § 103(a) has been rendered moot.

Overall, then, Applicants respectfully submit that claims 57 & 58, in addition to claims 63-69, 74, 76, 77 & 79-82, which depend directly or indirectly from claims 57 or 58, are not rendered obvious by the Baum '293 patent in view of the Schnepf reference. Therefore, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 63-69, 74, 76, 77 & 79-82 under § 103(a).

The Office Action states that claim 71 remains rejected and claim 76 is rejected under § 103(a) as being unpatentable over the Baum '293 patent in view of U.S. Patent No. 6,294,711,

issued to Meulewaeter et al. (the "Meulewaeter '711 patent"). However, amended claim 71 now contains the features involving a chimeric gene comprising a 35S promoter of Cauliflower Mosaic Virus, a leader sequence from the chlorophyl a/b binding protein gene from Petunia, a DNA sequence encoding the TpssuAt transit peptide, the DNA of claim 57, or a DNA encoding the protein of SEQ ID NO: 2 or an insecticidally-effective fragment thereof, and a 3' transcript termination and polyadenylation region of the 35S gene from Cauliflower Mosaic Virus. Therefore, the Baum '293 patent in view of the Meulewaeter '711 patent does not teach or suggest all the limitations of amended claim 71. Consequently, Applicants respectfully request the Examiner to reconsider and withdraw the § 103(a) rejection of claim 71 and claim 76, which depends from claim 71 in the alternative.

The Office Action states that claim 72 remains rejected under § 103(a) as being unpatentable over the Baum '293 patent in view of the Meulewaeter '711 patent and further in view of U.S. Patent No. 6,489,542, issued to Corbin et al. Claim 72 has been cancelled. Thus, the rejection of claim 72 under § 103(a) has been rendered moot.

The Office Action also states that claim 73 is rejected under § 103(a) as being unpatentable over the Baum '293 patent in view of the Meulewaeter '711 patent and further in view of U.S. Patent No. 6,114,608, issued to Mettler et al. Claim 73 has been cancelled. Thus, the rejection of claim 73 under § 103(a) has been rendered moot.

The Office Action additionally states that claims 75 & 78 are rejected under § 103(a) as being unpatentable over the Baum '293 patent in view of U.S. Patent No. 6,156,573, issued to Malvar et al. Claims 75 & 78 have been cancelled. Therefore, the rejection of claims 75 & 78 under § 103(a) has been rendered moot.

**CONCLUSION**

Applicants respectfully request entry of the above claim amendments.

All of the stated grounds of objection and rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

In view of the above claim amendments and remarks, early notification of a favorable consideration is respectfully requested. A check in the amount of \$1,020.00 is enclosed to cover the three-month extension of time fee. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

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